

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE

IN RE: VALSARTAN N-  
NITROSODIMETHYLAMINE (NDMA),  
LOSARTAN, and IRBESARTAN PRODUCTS  
LIABILITY LITIGATION

Civil No. 19-2875 (RBK/JS)

**MEMORANDUM OPINION AND ORDER**

This Opinion and Order addresses an incessant dispute that plagues complex litigation - that is, whether a Confidentiality designation pursuant to a Discovery Confidentiality or Protective Order is appropriate and necessary.<sup>1</sup> Since the parties' dispute is emblematic of what this Court regularly grapples with, the Court welcomes the opportunity to expound on the issue. The present dispute involves plaintiffs' challenge to five (5) Confidentiality designations made by Torrent.<sup>2</sup> Torrent wants to maintain its designations so that the distribution of its documents is limited

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<sup>1</sup> Disputes regarding the over designation of Confidential documents is not harmless. These disputes result in substantial unnecessary distractions for the parties and the court. The disputes also consume substantial resources and time unrelated to the merits of the underlying dispute. In addition, over designation causes administrative headaches since parties have to be concerned about distribution limits as well as redactions and sealing requests. See In re Ullico Inc. Litigation, 237 F.R.D. 314, 318 (D.D.C. July 11, 2006) (over designation of documents as Confidential causes unnecessary "logistical restraints" and "obstacles" for the non-designating party).

<sup>2</sup> "Torrent" is short for Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc.

to a small group of defined persons. Plaintiffs object. For the reasons to be discussed, plaintiffs' challenge is sustained and, accordingly, Torrent's Confidentiality designations are stricken. The Court also grants plaintiffs' request that the Court's ruling as to Torrent's "exemplar" documents be applied to the universe of Torrent's designations.

### Background

This MDL concerns plaintiffs' contention that defendants manufactured, distributed, sold, etc., generic Valsartan prescription high blood pressure medication that was contaminated with cancer causing chemicals. Plaintiffs maintain the contamination caused the users to incur cancer and they seek personal injury, medical monitoring and economic damages. Defendants do not deny that some of their Valsartan contained "impurities," but deny the Valsartan caused any damage or injury. The current main targets of plaintiffs' discovery are the manufacturers of Valsartan's active pharmaceutical ingredient ("API") as well as the finished dose manufacturers ("FDM"). Torrent is an FDM. The contamination at issue was first revealed in the summer of 2018 which resulted in worldwide recalls of Valsartan initiated by, inter alia, the FDA, foreign regulatory bodies and some defendants.

Shortly after the Valsartan recalls were initiated litigation ensued. This Court has been managing the litigation since its outset. For the past several months Torrent and the other manufacturing defendants have been producing their responsive documents and ESI. These productions are largely completed and fact depositions of certain plaintiffs and the lead defendants are about to begin. Plaintiffs challenge Torrent's confidentiality designations of five (5) documents or email chains. Although only the five documents are presently at issue, plaintiffs asked Torrent to use the Court's rulings as to these documents as exemplars for all of Torrent's designations. Torrent objects to the request.

Plaintiffs argue Torrent's documents should be de-designated for procedural and substantive reasons. To start with, plaintiffs argue de-designation is appropriate because Torrent did not follow the Court Ordered procedure when parties dispute a Confidentiality designation. Specifically, plaintiffs argue Torrent did not raise the present dispute with the Court as is required by the Order. As a result, plaintiffs argue the Order requires that Torrent's designations are waived. Torrent did not dispute this argument. As to the parties' substantive dispute, plaintiffs argue Torrent's documents do not satisfy the Court Ordered criteria to qualify for confidentiality protection. In response Torrent argues its documents should remain confidential since "(1) they are non-public and (2) they contain proprietary information and highly

sensitive commercial information regarding Torrent's internal processes, investigations, and communications with its customers that, if disclosed, could cause competitive harm." Liaison Counsel's Dec. 8, 2020 Letter at 6, Doc. No. 655. Torrent also argues plaintiffs' request to use its five documents as exemplars is "overbroad and unduly burdensome." Id. at 7. Instead, Torrent insists that as to every disputed designation plaintiffs must "describe with particularity the documents or information in question and shall state the grounds for objection." Id.

The definition of "Confidential Information" in the Discovery Confidentiality Protective Order entered on June 26, 2019 [Doc. No. 139] is dispositive of the parties' dispute. The Order defines the term in relevant part as follows in paragraph 9.B:

The term "CONFIDENTIAL INFORMATION" as used in this Protective Order means all information produced by any party in the course of discovery or other proceedings in this case (electronic or otherwise) which is proprietary, trade secret and/or highly sensitive commercial information, and which is believed in good faith by the Producing Party to have the potential, if disclosed, for causing competitive harm to it or giving a competitive advantage to others, and/or which is not publicly available and which a party believes in good faith to be subject to federal, state, or foreign data protection laws or other similar privacy obligations imposed by law.

Pursuant to the Order a party may designate a document as Confidential and, if so, the information may only be used for purposes of this litigation and may only be disclosed to designated

persons. Id. ¶¶22, 24. Disclosure of Confidential Information other than in accordance with the Order may subject the disclosing person to sanctions. Id. ¶26. Parties intending to file Confidential Information with the Court must file a motion to seal the materials in accordance with paragraph 31.

The procedure for objecting to a Confidentiality designation is set forth in paragraph 20. Counsel for the objecting party must serve the producing party with an objection "which shall describe with particularity the documents or information in question and shall state the grounds for objection." Thereafter, the producing party must respond in writing within twenty-one (21) days and "shall state with particularity the grounds" for asserting the document is Confidential. The Order provides that, "[i]f no timely written response is made to the objection, the challenged designation will be deemed to be void." If a timely response is made the parties have fourteen (14) days to resolve the dispute. If the dispute is not resolved, "the proponent of the designation being challenged shall present the dispute to the Court within twenty-one (21) days of its written response before filing a formal motion regarding the challenged designation." Importantly, the Order provides that the "failure to request a conference or to file [a] motion shall operate as a waiver of the disputed designation." See Order ¶20.

Torrent supports its position with the affidavit of its Chief Executive Officer, Sanjay Gupta. Gupta generally avers, "the five documents at issue are documents that Torrent would not reveal to the public and contain proprietary information and highly sensitive commercial information regarding Torrent's internal processes, investigations, and communications with its customers that, if disclosed, could cause competitive harm."

### Discussion

Confidentiality Orders are routinely entered in complex litigation. Orders of this type serve the beneficial purposes of expediting the flow of discovery material, facilitating the prompt and efficient resolution of disputes, adequately protecting confidential information, and ensuring that protection is afforded to discovery so entitled. In re Xyprexa Injunction, 474 F. Supp. 2d 385, 397 (E.D.N.Y. 2007). However, Courts must be vigilant to assure Confidentiality Orders are not overused and are only used for legitimate purposes. As one court has aptly noted, "the purpose of entering a protective order is not to insulate a party from the annoyance, embarrassment, oppression, or burden that may be caused by having to defend claims of wrongdoing the details of which appear in materials produced during discovery." American Financial Svcs., Inc. v. Reserve Fund, C.A. No. 08-5219 (PAM/JJK), 2008 WL 11456114, \*3 (D. Minn. Dec. 15, 2008).

Torrent has the burden of showing that a Confidentiality designation is appropriate. Cipollone v. Liggett Group, Inc., 785 F. 2d 1108, 1121 (3<sup>rd</sup> Cir. 1986). As Torrent recognizes, this designation only applies to "proprietary, trade secret and/or highly sensitive commercial information" that has the "potential, if disclosed, for causing competitive advantage to others." The Third Circuit has written that "[b]road allegations of harm, unsubstantiated by specific examples or articulated reasoning" are not sufficient. Id. In addition, the harm at issue "must be significant, not a mere trifle." Id. In Deford v. Schmid Prod. Co. A Div. of Schmid Labs, 120 F.R.D. 648, 653 (D. Md. 1987), the Court wrote, " [w]here a business is the party seeking protection, it will have to show that disclosure would cause significant harm to its competitive and financial position. That showing requires specific demonstrations of fact supported where possible by affidavits and concrete examples, rather than broad, conclusory allegations of potential harm."<sup>3</sup>

In Pansy v. Stroudsburg, 23 F. 3d 772 (3<sup>rd</sup> Cir. 1994), the court expounded on the burden to justify confidentiality. The key

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<sup>3</sup> Plaintiffs' citation to the Court's decision in In re: Benicar (Olmesarten) Products Liab. Litig., C.A. No. 15-2606 (RBK/JS), 2016 WL 266353, at \*3 (D.N.J. Jan. 21, 2016), is inapposite. That decision addressed whether to seal a document filed on the public docket. The present dispute concerns whether a document produced in discovery should remain confidential.

is that good cause must be shown. Id. at 786. "Good cause" is established by showing that disclosure will work a clearly defined and serious injury to the party seeking confidentiality. Id. Importantly, "[c]ircumstances weighing against confidentiality exist when confidentiality is being sought over information important to public health and safety." Id. at 787. Also, a court "should consider whether the case involves issues important to the public." Id. at 788. Whether to uphold a Confidentiality designation is a discretionary decision left to the court. Quoting from a leading law review article the Third Circuit has written:

Discretion should be left with the court to evaluate the competing considerations in light of the facts of individual cases. By focusing on the particular circumstances in the cases before them, courts are in the best position to present both the overly broad use of [confidentiality] orders and the unnecessary denial of confidentiality for information that deserves it.

Id. at 789 (citation omitted).

Torrent's request to maintain its Confidentiality designations is denied for procedural and substantive reasons.

1. Torrent Did Not Comply With the Procedural Requirements in the Order

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Initially, Torrent's Confidential designations are stricken because it did not comply with the Court Ordered procedure for responding to plaintiffs' challenge. The straightforward procedure to challenge and defend a Confidentiality designation is set forth in paragraph 20 of the Order. As noted earlier, in the



first instance the objecting party is required to serve the producing party with its written objection to a designation stating the grounds for the objection. Thereafter, the producing party must respond in twenty-one (21) days stating its grounds for the objection. If no timely written response is made to the objection, the challenged designation will be deemed to be void. If a timely response is served, counsel are required to meet and confer within fourteen (14) days of the response. If the dispute is not resolved, "the proponent of the designation being challenged shall present the dispute to the Court" within twenty-one (21) days of the date of the producing party's response. Importantly, the "failure to request said conference, or to file the motion shall operate as a waiver of the disputed designation." These two deadlines may be changed, "for good cause for specific challenges on informal application to the Court." See Order ¶20.

Plaintiffs challenged Torrent's designation on October 27, 2020. Torrent replied on November 10, 2020 by stating it was "standing on its confidential designations." Torrent followed up on November 11, 2020 and justified its designations by simply stating the challenged documents were "not public." During the parties meet and confer on November 13, 2020, Torrent reiterated that its documents were "non-public" and added that its documents were "sensitive." Torrent told plaintiffs that if a document was not publicly available, for example via "Google," then it

considered the document confidential. Doc. No. 654 at 5. On December 3, 2020, plaintiffs advised Torrent that it was required to bring the parties' dispute to the Court's attention and its failure to do so operated as a waiver of the disputed designation. Torrent did not contact the Court. As a result, plaintiffs brought the issue to the Court's attention in their December 8, 2020 letter. [Doc. No. 654]. Torrent's response to plaintiffs' letter was included in defense liaison counsel's December 8, 2020 letter. [Doc. No. 655].<sup>4</sup>

Torrent's actions fell short of what is required under the Order and, therefore, its Confidential designations are waived. Pursuant to the Order Torrent, not plaintiffs, were required to bring the parties' dispute to the Court's attention. Torrent did not do this. Nor did Torrent request an extension of time from the Court. Since Torrent violated the Court's Order, the Court's task is to decide the relief to be granted. In re Valsartan, C.A. No. 19-2875, 2020 WL 7054284, at \*6 (D.N.J. Dec. 2, 2020). Here the Court is not faced with a difficult decision concerning the relief to be granted since this is spelled out in the Order. The Order provides that if it is not complied with the disputed Confidentiality designations are waived. Therefore, the Court rules that Torrent waived its

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<sup>4</sup> Since Torrent did not dispute plaintiffs' summary of events, the Court assumes plaintiffs' summary is accurate.

Confidentiality designations and these are stricken. Torrent has no grounds to object to the Court's ruling since the Court is merely following the directives in the Order that was entered by consent. Further, plaintiffs put Torrent on specific notice of what was required but Torrent chose not to comply with the Order.<sup>5</sup>

2. Torrent Has Not Satisfied its Burden to Show That it Designated "Proprietary, Trade Secret and/or Highly Confidential Information," or That it Will Suffer a Particularized Serious Harm if its E-mails are De-Designated

The following is a summary of Torrent's five documents or email chains at issue:

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<sup>5</sup> Torrent's oversight is not inconsequential. Plaintiffs undoubtedly would prefer to devote their resources to important substantive issues. Also, plaintiffs had no choice but to raise this dispute with the Court when it was rightly Torrent's responsibility. Chaos will result if the parties do not adhere to the Court's Orders. Further, the Court would be justified in ruling against Torrent because of its original baseless response to plaintiffs' objection. Torrent's original objection that its Confidentiality designations were justified because its documents were not "public or "they were "sensitive" was frivolous and quite possibly may evince an intent to delay or obstruct. See Stroup v. United Airlines, Inc., C.A. No. 15-01389-WYD-CBS, 2016 WL 7176717, at \*11 (D. Colo. Sept. 16, 2016) (an improper designation of a document as confidential, like the improper certification of a discovery response under Rule 26(g), subjects the designator to the risk of sanctions)(citing cases). It is true that the definition of Confidential Information in the Order provides that non-public information may be designated Confidential. However, this is only in the instance when the designated information is "subject to federal, state, or foreign data protection laws or other similar privacy obligations imposed by law." Torrent has not argued that this criteria is applicable.

1. Numbers 6126 to 6217

These emails were sent between July 6, 2018 to August 17, 2018. The emails generally concern an inquiry to Torrent concerning whether the manufacturer/API sources for Torrent's Valsartan that were recalled in Europe were distributed in the United States.

2. Number 6097

These emails are dated July 12 and 19, 2018, and concern updates from Torrent to AmerisourceBergen ("AB") regarding the "impurity" in ZHP's Valsartan API. Torrent advises AB that there are no Torrent products in the United States that use the suspected synthesis that caused the impurity. Torrent also states it was advised by the FDA it was free to resume distribution of its products.

3. Numbers 72713 to 72716

These internal Torrent emails were sent between August 17, 2018 to August 18, 2018. They generally concern discussions about "NDMA above actionable levels," recalls and testing to identify impurities.

4. Number 100222

This is an August 3, 2018 "NOTIFICATION" from ZHP to "To whom it may concern" regarding the fact that trace amounts of NDMA was detected in Valsartan API using the "Old Process." ZHP advises the recipients "to put on hold the use of the API[.]"

5. Numbers 100153 to 100162

These emails were sent between June 20, 2018 to July 26, 2018. The emails concern ZHP's notice to Torrent about "Genotoxic impurities" regarding the Valsartan API ZHP supplied. Torrent sent the emails to its customer, Orion, and then engaged in discussions about the notice and potentially contaminated Valsartan. These emails discuss, inter alia, exposure limits for the chemical NDMA. Orion advised Torrent that it started a recall of Valsartan in Finland. Thereafter, discussions took place regarding who was responsible for the costs and expenses resulting from the recall.

As to the five email chains at issue, Torrent's affidavit justifies its Confidentiality designations as follows:

- De-designating "would cause Torrent harm because it would give competitors insight as to how Torrent manages investigations, recalls, and its customer relationships."
- De-designation "would cause Torrent harm because it would give competitors insight as to how Torrent manufactures finished dose Valsartan, manages investigations and recalls, and its customer relationships."
- De-designation "could ... potentially harm Torrent's relationship with its customers, who expect that Torrent will keep their communications confidential."
- De-designation "would cause Torrent harm by giving competitors insight as to how Torrent investigates alleged impurities, manages investigations and recalls, communicates with its customers, and evaluates and responds to customer claims for reimbursement and damages."
- De-designation "would cause Torrent harm because it would give competitors insight into Torrent's communications with its suppliers and the process used to make the API Torrent used in its finished dose Valsartan."

In order to determine if Torrent's designations should be stricken it was essential that the Court review for itself the documents at issue. It is not the case that the Court must accept Torrent's affidavit at face value. The Court is not required to give credence to Torrent's conclusory self-serving affidavit that is inconsistent with the Court's independent review of Torrent's documents. See Daubert v. NRA Group, LLC, 861 F. 3d 382, 391-92

(3<sup>rd</sup> Cir. 2017). Otherwise, a party can justify its designations by simply supplying a self-serving affidavit.<sup>6</sup>

Having reviewed Torrent's documents in detail, the Court finds that Torrent's Confidentiality designations are stricken for two substantive reasons. One, the emails do not contain "proprietary, trade secret and/or highly confidential information." Two, the emails do not have the potential "for causing [significant] competitive harm to [Torrent] or giving a competitive advantage to others."

At bottom, Torrent's emails involve what appears to be routine business communications. Albeit, the emails were prepared in response to what appears to be an unprecedented situation. Although Torrent understandably may not want its documents "public," it is not the case that merely because a document may be

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<sup>6</sup> Numerous examples of the affiant's misleading statements may be given but two examples will suffice. As to document 6097 the affiant avers that the document "provides details regarding the manufacturing process used by [ZHP]" and "contains sensitive commercial information regarding Torrent's API suppliers[.]" However, the only reference to ZHP's manufacturing process in document 6097 is that ZHP "currently [has] 3 routes by which they manufacture Valsartan." This information is not sensitive and is undoubtedly referenced in publicly available documents. Also, as to document 100222, Torrent's affiant avers it is a "sensitive communication." However, the document appears to merely be a form "NOTIFICATION" ZHP sent to its customers to the effect that the chemical NDMA was present in ZHP's Valsartan API and the customer should "put on hold the use of the API[.]" There is nothing commercially sensitive or confidential about this communication and the document contains no indication that its distribution should be kept secret.

harmful, uncomfortable or embarrassing that a Confidentiality designation is appropriate. "[C]ourts have emphatically held that a protective order cannot be issued simply because it may be detrimental to the movant in other lawsuits." Nestle Foods Corp. v. Aetna Cas. & Sur. Co., 129 F.R.D. 483, 486 (D.N.J. 1990).

Torrent's affidavit overstates its case. Torrent's emails do not contain any references, nor does Torrent cite to, a proprietary procedure or practice. Nor does Torrent's affidavit specifically refer to anything of the sort. Further, although Torrent argues its customers may gain insight into how it handled its recall and investigation, there is no support to show that Torrent did anything different than any other similarly situated company. There also is no evidence that Torrent's approach to the recall and the way it handled its investigation, recall and customer communications, was proprietary or secret. Further, nothing in the emails reflect a particular concern or worry by the authors of the emails that the distribution of the emails should be limited. In addition, none of the emails list or reference proprietary formulas or ingredients other than general references that are likely accessible in documents prepared by or filed with the FDA. Also, none of the emails discuss or reference Torrent's business plans, revenues, or profits.

Torrent argues its emails are "confidential" because this is what its clients expected. This is not an acceptable basis to justify the Confidential designation of a routine business communication. Otherwise, large swatches of routine emails would be kept under wraps. "General allegations of injury to reputation and client relationships or embarrassment that may result ... is insufficient to justify judicial endorsement of an umbrella confidentiality agreement." See Barnes Found. Twp. of Lower Merion, C.A. No. 96-372, 1996 WL 729885, at \*3 (E.D.Pa. Dec. 6, 1996).

Torrent not only failed to satisfy its burden that its emails contain "proprietary, trade secret and/or highly confidential information," but it also has not shown that it will be significantly harmed by the release of its emails. Where a party seeks confidentiality protection it must show that "disclosures would cause significant harm to its competitive and financial position." Deford v. Schmid Prod.Co. a Div. of Schmid Labs., 120 F.R.D. 648, 653 (D. Md. 1987). This requires a "specific demonstrations of fact, supported where possible by affidavits and concrete examples, rather than broad, conclusory allegations of potential harm." Id. Torrent must show "significant harm" will result to its competitive and financial position to justify its designation. Id. The Third Circuit has held that in order to justify a Confidentiality designation it must be shown that



disclosure will work a clearly defined and serious injury to the party seeking closure. The injury must be shown with specificity. Pansy, 23 F.3d at 786 (citation omitted). As noted earlier, the harm "must be significant, not a mere trifle." Cipollone, 785 F. 2d at 1121.

Torrent's affidavit does not support a showing that a particularized serious harm would or could result from the de-designation of its documents. The affidavit merely contains generalized references to harm that allegedly would occur from de-designation. Torrent does not supply a single particularized example that any serious or substantial harm will result. Perhaps this is understandable in view of the Court's conclusion that Torrent's emails reflect routine business communications in response to an exigent situation. Torrent will not be seriously harmed if its competitors or the general public knows that it responded to a recall the same way similarly situated companies respond.

Torrent argues plaintiffs' application should be denied since, "Plaintiffs have not articulated any need for [its] documents to be de-designated or prejudice from their designation[.]". Doc. No. 684 at 9. This argument is frivolous. Torrent ignores the fact that pursuant to the Order it has the burden to justify confidentiality, not plaintiffs. Torrent also

ignores the fact that plaintiffs' need for de-designation or prejudice resulting from a Confidentiality designation is not a relevant factor to consider.

### 3. Torrent Shall Use the Court's Substantive Ruling as an Exemplar for Similar Designated Documents

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The last issue the Court needs to address is plaintiffs' request that the Court rule that the documents it reviewed be used as exemplars to guide Torrent in de-designating similar documents. As to the Court's waiver ruling, plaintiffs' request is denied. The Court rules that its waiver ruling only applies to the emails at issue. It would be inequitable to rule that Torrent waived its Confidentiality designations as to possibly tens of thousands of documents when only five documents are at issue and Torrent was not on notice that plaintiffs would make a waiver request as to all of Torrent's documents.

Torrent is not as fortunate regarding the Court's substantive ruling. As to the ruling that Torrent's emails are not Confidential, Torrent is directed to apply the ruling to all of its document designations. It would be wasteful to require plaintiffs to specifically list every designation challenge when Torrent is already on notice of the Court's ruling. As the party with the burden of proof to support a Confidentiality designation, the burden is fairly placed on Torrent to remove its designations

that are inconsistent with the Court's ruling. The Court agrees with plaintiffs' argument: "[t]hese documents are so obviously outside of the narrow band of documents arguably entitled to confidentiality that Plaintiffs request relief designed to avoid burdening Plaintiffs and the Court with a steady stream of challenges to facially inappropriate designations." Doc. No. 654 at 8.

Torrent argues the use of exemplars is inconsistent with the language in the Order. The Court disagrees. It is true, as Torrent argues, the Order provides that plaintiff must "describe with particularity the document or information in question and shall state the grounds for objection." However, this language does not address the situation where the Court has already ruled on an issue and plaintiffs are simply asking Torrent to implement the Order. The use of an exemplar subset of documents for use as guidance to be applied to a larger set is an acceptable practice. See Rockwell Automation, Inc. v. Radwell International, Inc., C.A. No. 15-5246 (RBK/JS) 2019 WL 1864198 (D.N.J. April 25, 2019), aff'd on appeal. See December 31, 2019 Order, Doc. No. 553.<sup>7</sup>

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<sup>7</sup> In view of the Court's ruling that Torrent's designations are procedurally and substantively deficient, there is no need to engage in the good cause analysis discussed in Pansy.

Conclusion and Order

For all the foregoing reasons plaintiffs' application is GRANTED.

Accordingly, it is hereby ORDERED this 8th day of January 2021, as follows:

1. Torrent's "Confidentiality" designations as to the five documents referenced in this Order are STRICKEN.
2. Torrent shall apply the Court's ruling as to its exemplar documents to all of its Confidentiality designations. To the extent similar documents are designated Confidential, the designations shall be removed.
3. By February 26, 2020, Torrent shall notify plaintiffs which of its Confidentiality designations, if any, are removed. To the extent any disputes exist they shall be presented to the Court in the manner provided for in paragraph 9 of the Confidentiality and Protective Order.

s/ Joel Schneider

JOEL SCHNEIDER

United States Magistrate Judge